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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,298	ALLEN, ANN DE WEES	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☒ Claim(s) 5,8,12 and 15 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 20 October 2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are presented for examination.

Acknowledgement is made of the present application as a proper continuation of U.S. Patent Application No. 08/938,801 filed September 26, 1997, now U.S. Patent No. 6,608,109, which is a continuation of U.S. Patent Application No. 08/784,132 filed January 15, 1997, now abandoned, which is a continuation of U.S. Patent Application No. 08/562,395 filed November 24, 1995, now abandoned, which is a continuation of U.S. Patent Application No. 08/215,667 filed March 22, 1994, now abandoned, which is a continuation of U.S. Patent Application No. 07/793,837 filed November 20, 1991, now abandoned. **In light of the fact that the presently claimed subject matter is fully supported by the disclosure of parent application 07/793,837, Applicant has been granted the benefit of the parent application. The effective filing date of the present application is November 20, 1991.**

Applicant's Information Disclosure Statement (IDS) filed October 20, 2003 has been received and entered into the application. As reflected by the attached, completed copy of substitute form PTO-1449 (two pages total), the Examiner has considered the cited references.

Objection to the Oath/Declaration

The oath or declaration is defective. The oath or declaration is defective because the specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602. Applicant has marked the box stating that the specification "is attached hereto" and further marks the box stating that the specification "was filed on November 20, 1991 as U.S. Application Serial No.", but fails to provide the application number in which the specification

was filed. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by serial number and filing date is required. See MPEP §§ 602.01 and 602.02. Applicant should check **only** the box relating to the specification having been "filed on November 20, 1991 as U.S. Application Serial No." and provide the application number (i.e., 07/793,837).

Objections to the Claims

Claim 5 is objected to because the claim recites "which has a 700 mg, or less, of choline", where it should be amended to properly read ---which has ~~a~~ 700 mg, or less, of choline--- for clarity.

Claim 8 is objected to because a space should be inserted between the word "claim" and the number "6" in line 1 of the claim.

Claim 12 is objected to for reciting "an effective amount L-arginine", which should be amended to read ---an effective amount of L-arginine--- for clarity.

Claim 15 is objected to for reciting a period after "1-10 g." in line 2 of the claim. Claims should not contain more than one period, provided that a period is not required to denote a decimal point. Appropriate correction to remove the extra period is required.

Objections to the Specification

The disclosure is objected to because of the following minor informalities:

(i) the word "dosages" is misspelled at line 3 of page 3 of the disclosure;

(ii) the word "stimulating" is misspelled at line 15 of page 4 of the disclosure; and

(iii) the word "high" is misspelled at line 20 of page 7 of the disclosure.

Appropriate correction is required.

Claim Rejection - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 2, 8 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The MPEP sets forth the following at §2173:

> "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (See MPEP §2173).

The term "about" in the expression "about 1.0 g to 60.0 g per serving" (see claim 2, for example) is a relative term that renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The use of such a term would invite subjective interpretations of whether or not a given dosage amount of L-arginine or vitamin C is included in or excluded from the present claims and what degree of variability outside the recited range is within the scope of the claims. It is the Examiner's position that the public would not be reasonably informed of the boundaries

of what constitutes infringement of the present claims.

The claims do not meet the tenor and express requirements of 35 U.S.C. §112, second paragraph and are properly rejected.

II Claims 4 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The parenthetical phrase "Calcium Pantothenate" following "Vitamin B5" in line 7 of each claim renders the claims indefinite. It is unclear which term is intended to limit the subject matter of the claim. Applicant has presented the terms in such a way as to intend to further limit the subject matter by reciting the use of calcium pantothenate. However, calcium pantothenate is a calcium salt of pantothenic acid, and is not pantothenic acid itself. Thus, the presence of the parenthetical phrase does not appear to further limit the claim, but rather renders the claim indefinite because it fails to delineate which term is meant to be the limiting term. As a result, the skilled artisan would not be reasonably informed of the metes and bounds of the claim and, thus, of what would constitute infringement of the present claims. Such is inconsistent with the tenor and express requirements of 35 U.S.C. 112, second paragraph, and, thus, the claims are properly rejected.

Applicant may wish to amend the claims by eliminating the term that is not intended to further limit the subject matter of claims 4 and 10.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287; 1972).

Winitz teaches an amino-acid food composition comprising free amino acids (col.4, lines 30-31), such as L-arginine, L-leucine, L-valine or L-isoleucine, in combination with the vitamins d-calcium pantothenate and choline bitartrate (see Tables I and II, for example).

While the Examiner has considered the limitation "for stimulating muscle growth", such a recitation amounts to nothing more than a recitation of the intended use of the composition and fails to impart any physical or structural element(s) to the composition that is not already present in the composition of the prior art. Applicant's attention is further drawn to the MPEP at §2111.02 [R-2], which states:

"If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction...During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or

intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art...If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287; 1972) as applied to claim 1 above, and further in view of Durst (U.S. Patent No. 3,434,843; 1969) and Millman (U.S. Patent No. 4,871,550; 1989).

The differences between the Winitz reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the use of chromium or sodium borate; and

(ii) the particular dosage amounts of the present claims.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) It is acknowledged that Winitz is silent as to the use of chromium or sodium borate in the disclosed amino acid-nutrient composition. However, each was well known in the art to be as essential food nutrient and also that each was useful for the same therapeutic purpose of providing balanced nutrition. Durst teaches the use of sodium borate as an essential nutrient in the disclosed food composition intended to provide a completely balanced diet (see Durst, abstract and col.5, lines 17-27) and Millman teaches the use of chromium as a mineral useful for the preparation of a nutrient composition intended to provide substantially all of the essential nutrients (see Millman, abstract and col.8, lines 36-39). It would, therefore, have been obvious to a person of ordinary skill in the art to employ both chromium and sodium borate in combination with the composition disclosed by Winitz because each was known in the art to be successful for achieving the same therapeutic effect. Motivation to administer both compounds flows logically from the efficacy of each compound in providing dietary balance and nutrition as demonstrated in the prior art and also because each compound has been previously administered for the same therapeutic endpoints. In the absence of evidence to the contrary, it is generally *prima facie* obvious to use in combination two or more agents that have previously been used separately for the same purpose. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA).

(ii) Winitz expressly teaches variability in the dosage amounts of the components to be administered in the disclosed amino acid composition. Winitz states:

"As previously indicated, the amino acid components of a diet are selected to meet the normal metabolic needs of the subject and to maintain the desired nitrogen balance...Because of strong interdependencies between the required level of a given amino acid and the level of one or more of the other amino acids present in the diet, it is not practicable to establish a precise range

of levels for each of the amino acids (col.6, lines 17-33)...The relative amounts of the various components of the diet can be varied within fairly wide limits. The carbohydrate, vitamin and mineral component, of course, are selected to as to supply, respectively, adequate caloric value and to adequately meet the necessary daily minimum requirements for these components (col.11, lines 46-52)."

Thus, the determination of the optimum dosage regimen for the presently claimed active agent(s) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." While the present set of facts are not expressly drawn to percentages, but rather to mcg or mg amounts, such motivation is nonetheless relevant.

II Claims 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudman et al. ("Growth Hormone Treatment of Frailty In Men Over 60", *New England Journal of Medicine*, 1990), Dudrick et al. (U.S. Patent No. 5,026,721; 1991), and Boynton et al. (U.S. Patent No. 5,087,624; Issued 1992; Priority to 1987).

Rudman et al. teaches various agents that are capable of enhancing the release of growth hormone, such as arginine (see paragraph bridging col.2 of page 4 with col.1 of page 5), vitamin B5 and choline (page 5, col.1, lines 9-11 of the second to last paragraph and also last paragraph of col.1 of page 6), as well as boron (first two paragraphs of col.2 at page 6). Rudman et al. further teaches that a release of growth hormone, in turn, increases the muscle to fat ratio of the body and stimulates the immune system, as does arginine itself (page 4, col.1, first sentence of second to last paragraph). Rudman et al. also discloses that arginine was capable of speeding healing and increased resistance to cancer cells in experimental animals (last sentence of second to last paragraph of col.1 at page 4) and acknowledges the efficacy of vitamin C in protecting tissue from damage by superoxide radicals produced by macrophages to kill bacteria (see paragraph bridging cols. 1 and 2 of page 4).

Dudrick et al. teaches an amino acid nutritional supplement containing a mixture of biologically active amino acids including arginine, leucine, isoleucine and valine (see abstract and col.3, lines 34-47), which are preferably in the L-form, since the L-form is considerably more biologically active than the D-form (col.3, lines 30-33), for the purpose of enhancing physical performance (see abstract, for example), particularly an improvement in muscle growth and strength (col.2, lines 11-20). Dudrick et al. further teaches the incorporation of other vitamins, minerals, electrolytes or carbohydrates into the composition as required for sound

nutrition (col.4, line 67-col.5, line 3).

Boynton et al. teaches the use of chromic picolinate, a combination of chromium with picolinic acid, at a dose to provide about 10 to about 500 mcg of chromium per day, which can be used as an anabolic agent in animals (including both human and non-human mammals) to increase the lean body mass and to concomitantly decrease the percentage of body fat (col.4, lines 43-68).

The differences between the Rudman et al. reference, the Dudrick et al. reference and the Boynton et al. reference lies in that the references do not teach:

(i) concomitant administration of L-arginine, L-leucine, L-isoleucine, L-valine, chromium, choline, sodium borate and vitamin B5 in a method for stimulating muscle growth in a mammal;

(ii) concomitant administration of L-arginine and vitamin C for stimulating of an immune response; and

(iii) the particular dosage amounts of the present claims.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

(i) It is acknowledged that neither the Rudman et al. reference, the Dudrick et al. reference nor the Boynton et al. reference teaches the use of a composition comprising L-arginine, L-leucine, L-isoleucine, L-valine, chromium, choline, sodium borate and vitamin B5 for the therapeutic objective of stimulating or enhancing muscle growth. However, Rudman et

al. teaches the administration of arginine, vitamin B5 and choline, as well as boron, for enhancing the release of growth hormone and increasing the muscle to fat ratio, considered by the Examiner to be a teaching of increasing muscle mass (see Rudman et al., paragraph bridging col.2 of page 4 with col.1 of page 5, page 5, col.1, lines 9-11 of the second to last paragraph, last paragraph of col.1 of page 6 and first two paragraphs of col.2 at page 6). Dudrick et al. teaches the administration of amino acids, preferably in L-form, including arginine, leucine, isoleucine and valine, for the purpose of enhancing physical performance, particularly an improvement in muscle growth and strength (see Dudrick et al., abstract and col.2, lines 11-20 and col.3, lines 30-33) and Boynton et al. teaches the use of chromic picolinate, a source of chromium, for use as an anabolic agent in animals (including both human and non-human mammals) to increase the lean body mass and to concomitantly decrease the percentage of body fat (see Boynton et al., col.4, lines 43-68).

However, each of these individual components was well known in the art to be useful for the same therapeutic purpose of enhancing muscle mass or muscle growth. It would, therefore, have been obvious to a person of ordinary skill in the art to employ L-arginine, L-leucine, L-isoleucine, L-valine, chromium, choline, sodium borate and vitamin B5 in a method for stimulating muscle growth because each was known in the art to be successful for achieving the same therapeutic effect. Motivation to administer both compounds flows logically from the efficacy of each compound in providing dietary balance and nutrition as demonstrated in the prior art and also because each compound has been previously administered for the same therapeutic endpoints. In the absence of evidence to the contrary, it is generally *prima facie*

obvious to use in combination two or more agents that have previously been used separately for the same purpose. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA).

Furthermore, while Rudman et al. generally teaches the use of boron, whereas the present claims are drawn to the use of sodium borate, sodium borate was a compound well known in the art at the time of the invention as an essential nutrient amenable to combination with amino acids (see Durst, U.S. Patent No. 3,434,843; 1969). Use of sodium borate would have been well within the purview of the skilled artisan. Such a person would have been motivated to use sodium borate since a salt formulation of boron would, nevertheless, be a source of boron and it would also have been reasonably expected that sodium borate would exert the same or similar growth hormone release-enhancing effects as that of boron itself.

(ii) Rudman et al. teaches the efficacy of arginine in stimulating the immune system, which was further demonstrated by the increased speed of healing and increased resistance to cancer cells in experimental animals (last sentence of second to last paragraph of col.1 at page 4) and further acknowledges the efficacy of vitamin C in protecting normal tissue from damage by the superoxide radicals produced by macrophages during the course of killing bacteria. Rudman et al. also teaches that growth hormone activates macrophages by increasing their production of superoxide radicals (see paragraph bridging cols. 1 and 2 of page 4).

While the Rudman et al. reference does not expressly teach the administration of arginine in combination with vitamin C for the stimulation of an immune response, it would have been appreciated by the skilled artisan that the administration of arginine in order to stimulate the immune system would, in turn, increase the amount of growth hormone (see paragraph bridging col.2 of page 4 and page 5 and col.1-2 of page 5), which further increases the production of

superoxide radicals in order to kill bacteria. Thus, a surplus of superoxide radicals would be present in the tissues as a result of the administration of arginine for the objective of stimulating the immune system. The skilled artisan would have recognized that an excess of superoxide radicals would be detrimental to normal, healthy tissues, and that the administration of the antioxidant vitamin C would prevent damage to such tissues by the excess superoxide radicals. Therefore, it would have been obvious to the skilled artisan to administer arginine in combination with vitamin C in order to protect healthy tissues from damage by the increase in superoxide radicals present in the body as a result of the administration of arginine.

While Rudman et al. does not specifically state the administration of L-arginine, the broad disclosure of arginine is considered to include both enantiomers (L and D form), as well as the racemate of arginine. Furthermore, it was well known in the art that the L-formulations of amino acids were considerably more biologically active than the D-form, thus, motivating the skilled artisan to employ L-arginine rather than D-arginine in a method for stimulating an immune response (see Dudrick et al., col.3, lines 30-33).

(iii) The determination of the optimum dosage regimen for the presently claimed active agent(s) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the

absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan.

Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." While the present set of facts are not expressly drawn to percentages, but rather to mcg or mg amounts, such motivation is nonetheless relevant.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,608,109.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the '109 patent are not considered to be patentably distinct from each other because the patented claims clearly render the pending claims obvious.

The patented claims clearly provide for the administration of a composition of L-arginine, L-leucine, L-isoleucine, L-valine, boron, vitamin B5, chromium and choline for stimulating muscle growth, as well as the administration of L-arginine for the stimulation of an immune response. While it is acknowledged that the patented claims also recite other components, such as fructose (see patented claim 9, for example), lemon, lime, gamma oryzanol, or trans ferulic acid (see patented claim 15, for example), the present claims use the word "comprising", which is considered open transitional claim language and allows for the use of components other than those expressly recited with the active agents of the present claims (see MPEP §2111.03 [R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the use of additional components.

Furthermore, while the patented claims are drawn to the use of boron, where the present claims are drawn to the use of sodium borate, such is not considered to be a patentably distinct difference between the patented and the pending claims because each is employed to supply a source of boron, regardless of the source from which it is supplied.

Lastly, while it is noted that the dosage amounts of the patented claims differ from those of the pending claims, and also that the patented claims recite limitations drawn to particular pH values and weight ratios of components of the composition, the determination of the optimum dosage amounts, weight ratios and pH would have been a matter well within the purview of the skilled artisan, taking into account the age, sex, overall health and severity of disease of the patient and the desired therapeutic effect, and would not have been considered to differ significantly from the dosage amounts, weight ratios or pH of the pending claims.

Moreover, regarding the pH values, since the active agents of the patented claims are also in the pending claims, and also since such agents are being given for the very same therapeutic objectives, it is reasonably expected that the pH values of the composition of the pending claims would be the same or similar to those of the composition of the patented claims.

Accordingly, rejection of claims 1-15 of the present application is deemed proper over claims 1-15 of U.S. Patent No. 6,608,109 as claiming obvious and unpatentable variants.

Conclusion

The prior art made of record but not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent No. 5,576,351 to Yoshimura et al. ("Use of Arginine as an Immunostimulator").

Rejection of claims 1-15 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

July 21, 2005

RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614